

Docket No.: 101896-241 (DEP5293)
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Mark C. Boomer et al.

Application No.: 10/708,919

Filed: March 31, 2004

For: ADJUSTABLE-ANGLE SPINAL FIXATION
ELEMENT

Confirmation No.: 2918

Art Unit: 3733

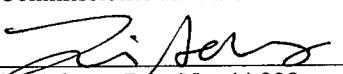
Examiner: D. C. Comstock

MS Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Lisa Adams, Reg. No. 44,238

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine SARL, a Johnson & Johnson company. DePuy Spine SARL derives its rights in this application by virtue of an assignment of the application by Mark C. Boomer, Raymond F. Murphy, and Bryan S. Jones to DePuy Spine SARL, recorded at Reel 015507, Frame 0582.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1, 2, 7-10, 13-20, 42, 43, and 46-50 are currently pending in the present application, Serial Number 10/708,919. According to the Office Action mailed on January 10, 2008, claims 1, 2, 7, 9, 13-16, 20, 42, and 43 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue; claims 1, 2, 13-20, 42, 43, 46, 48, and 49 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,509,328 of Lai; and claims 8, 10, 47, and 50 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,007,536 of Yue.

Accordingly, claims 1, 2, 7-10, 13-20, 42, 43, and 46-50 are subject to appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Office Action mailed on January 10, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention generally provides various angularly-adjustable spinal fixation devices that generally include first and second elongate members, a connecting feature formed on a terminal end of each elongate member, and a locking mechanism that is adapted to lock the first and second elongate members in a fixed positioned relative to one another. (See Para. 0027). Independent claim 1 recites a spinal fixation system, shown for example in FIG. 1A, that includes a first elongate member (e.g., 12a) having a female connector (e.g., 20a) with opposed arms (e.g., 23a, 23b) and a second elongate member (e.g., 12b) having a male connector (e.g., 20b) adapted to mate to the female connector. (See Para. 0028). At least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod. The first and second elongate members are coupled to one another such that the first and

second elongate members are angularly adjustable relative to one another. (See Para. 0030). The system further includes a mating element (e.g., 29) adapted to extend through the male and female connectors, and a fastening element (e.g., 27) adapted to mate to the male connector to cause the male connector to engage the mating element and lock the elongate members in a fixed position relative to one another. (See Para. 0032-0035). Claim 1 also recites a spinal anchor that is implantable in bone and that is configured to mate to at least one of the first and second elongate members.

Independent claim 42 recites a spinal fixation system, shown for example in Figure 1A and described at paragraphs 000028-0037, that includes first and second elongate members (e.g., 12a, 12b), each having a connecting feature (e.g., 20a, 20b) formed on a terminal end thereof. At least one of the first and second elongate members is a biocompatible, implantable-spinal fixation rod. The connecting features are coupled to one another such that the first and second elongate members are angularly adjustable relative to one another along a plane. A mating element (e.g., 29) is adapted to extend through the first and second elongate members, and a fastening element (e.g., 27) is adapted to extend into at least one of the connecting features along an axis that is substantially parallel to the plane to cause at least one of the connecting features to engage with the mating element to lock the first and second elongate members in a fixed position relative to one another. Claim 42 further requires a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members.

Independent claim 43 recites a spinal fixation system, shown for example in Figure 1A and described at paragraphs 000028-0037, that includes first and second elongate members (e.g., 12a, 12b) coupled to one another such that the first and second elongate members are angularly adjustable relative to one another. The angular adjustability of each elongate member is limited to a single plane. At least one of the first and second elongate members is a biocompatible, implantable-spinal fixation rod. Claim 43 further requires a mating element (e.g., 29) adapted to extend through the first and second elongate members, and a fastening element (e.g., 27) adapted to cause at least one of the first and second elongate members to engage the mating element to lock the elongate members in a fixed position relative to one another. The fastening element extends along an axis that is substantially parallel to the single plane of angular adjustability of each elongate member. Claim 43 further recites a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members.

Independent claim 46 recites a spinal fixation system, shown for example in Figure 1A and described at paragraphs 000028-0037, that includes a first elongate element (e.g., 12b) having a clamping mechanism (e.g., 20b) formed on a terminal end thereof, and a second elongate element (e.g., 12a) having a terminal end adapted to be received by the clamping mechanism on the first elongate element. At least one of the first and second elongate members is a biocompatible, implantable-spinal fixation rod. A fastening element (e.g., 27) is adapted to engage and close the clamping mechanism such that the second elongate member can be maintained in a fixed position relative to the first elongate member. Claim 46 further recites a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether the Examiner improperly rejected claims 1, 2, 7, 9, 13-16, 20, 42, and 43 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue (“Yue”).
- B. Whether the Examiner improperly rejected claims 1, 2, 13-20, 42, 43, 46, 48, and 49 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,509,328 of Lai (“Lai”).
- C. Whether the Examiner improperly rejected claims 8, 10, 47, and 50 pursuant to 35 U.S.C. §103(a) as being obvious over Yue.

VII. ARGUMENT

A. Rejection Pursuant to 35 U.S.C. 102(b) Over Yue

1. *The Scope and Content of the Prior Art*

As shown in FIGS. 1A, 1B, and 1C of Yue, which are reproduced herein, Yue discloses an orthopedic plate for use in correcting problems with the long bones of the body, such as the shoulder, knee, ankle, and hip. The device of Yue includes a blade (1) that is pivotally coupled using a pivot pin to a side plate (2) having a worm gear mechanism (3) that includes an adjustment portion (4), i.e., a screw, that engages a plurality of teeth formed on a portion of the blade (1). In use, the blade (1) is inserted into bone and the plate (2) is mated to bone with screws extending through screw holes (5)

formed in the plate (2). The worm gear adjustment portion (4) can be turned to manipulate the worm gear mechanism (3) and adjust the angle between the plate (2) and the blade (1).

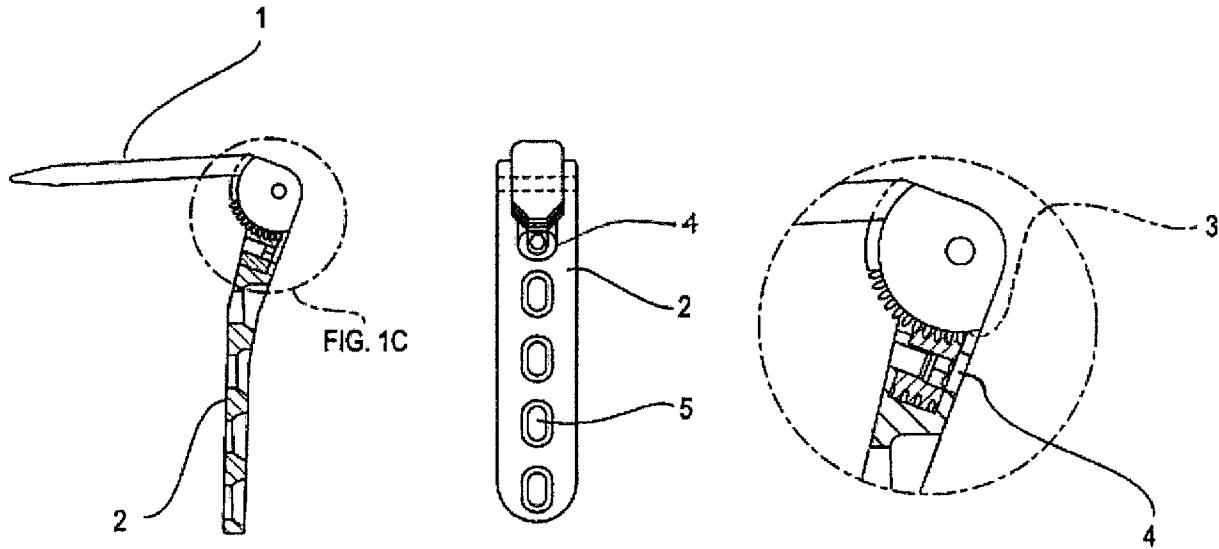


FIG. 1A

FIG. 1B

FIG. 1C

2. The Examiner's Rejection

Claims 1, 2, 7, 9, 13-16, 20, 42, and 43 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue ("Yue"). The Examiner argues that the blade portion (1) and the side plate (2) of Yue form the first and second elongate members recited in independent claims 1, 42, and 43. The Examiner asserts that the plate (2) includes a female connector having arms that receive a male connector, referring to FIG. 1B. The Examiner further argues that a bore (also shown in FIG. 1B) extends through the male and female connector components to allow rotation about a cylindrical mating element attached to the female connector, and that the worm gear portion (4) forms the claimed fastening element mated to the female connector. The Examiner also asserts that both the plate (2) and the blade (1) are capable of being implanted and used for spinal applications, and that an "end portion can function as a clamp when, for example, it is urged against an opposing portion of the device about an object." (January 10, 2008 Office Action, page 3).

3. Yue Does Not Teach The Claimed Invention

a. Independent Claims 1, 42, and 43

Independent claim 1 recites a fastening element adapted to mate to the male connector to cause the male connector to engage a mating element and lock the elongate members in a fixed position relative to one another, as required by claim 1. Independent claim 42 recites a fastening element adapted to extend into at least one of the connecting features to cause at least one of the connecting features to engage with the mating element to lock the first and second elongate members in a fixed position relative to one another. Independent claim 43 recites a fastening element that is adapted to cause at least one of a first and second elongate member to engage a mating element to lock the elongate members in a fixed position relative to one another. Accordingly, claims 1, 42, and 43 each generally require that the fastening element *cause* the male connector to *engage* the mating element. Yue does not teach or even suggest such a configuration.

Assuming, as the Examiner argues, that the blade portion (1) forms the second elongate member with the male connector and that the side plate (2) forms the first elongate member with the female connector (since the plate (2) includes arms that receive the blade (1)), the only component of Yue that could be considered to be the claimed mating element is the pivot pin that connects the blade portion (1) and the side plate (2). Thus, the adjustment portion (4), i.e., the adjustment screw or worm on the worm gear, must form the claimed fastening element since it is the only part of Yue that locks the blade (1) and the plate (2). The adjustment portion (4), however, does not *cause* the male connector, i.e., the blade (1), *to engage the mating element*, i.e., the pivot pin. The worm gear adjustment portion (4) is merely used to adjust the angle between the blade portion (1) and the side plate (2). The pivot pin is never engaged by the blade (1) or the plate (2). Rather, the pivot pin is always freely rotatably disposed through the blade portion (1) and the side plate (2). Accordingly, Yue clearly fails to teach a fastening element that causes a male connector to engage a mating element. This alone is sufficient to render claims 1, 42, and 43 allowable over Yue.

Independent claims 1, 42, and 43 therefore distinguish over Yue and represent allowable subject matter. Claims 2, 7, 9, 13-16, and 20 are allowable at least because they depend from claim 1.

b. Dependent Claim 7

Claim 7 recites that the first and second elongate members each comprise a biocompatible, implantable spinal fixation rod. The Examiner asserts that the blade (1) and the plate (2) form the claimed first and second elongate members. Neither the blade (1) nor the plate (2) are spinal fixation rods as this term is generally understood by a person having ordinary skill in the art. The term “spinal fixation rod” is a term that is well known to a person having ordinary skill in the art, and the term certainly would not be understood to refer to any type of implant, such as the blade (1) and plate (2) of Yue. Accordingly, dependent claim 7 distinguishes over Yue and represents allowable subject matter.

c. Dependent Claim 9

Claim 9 recites that the first elongate member is a biocompatible, implantable spinal fixation rod and second elongate member is a spinal fixation plate. The Examiner asserts that the blade (1) forms the claimed second elongate member and the plate (2) forms the first elongate member. As explained above with respect to claim 7, neither the blade (1) nor the plate (2) form a “spinal fixation rod” as this term is generally understood by a person having ordinary skill in the art. Accordingly, dependent claim 9 distinguishes over Yue and represents allowable subject matter.

d. Dependent Claim 10

Claim 10 recites that the first elongate member has a diameter that is different than a diameter of the second elongate member. The Examiner asserts that the blade (1) forms the claimed second elongate member and the plate (2) forms the first elongate member. Since both the blade (1) and the side plate (2) have a flattened shape, neither component has a diameter at all. Accordingly, dependent claim 10 distinguishes over Yue and represents allowable subject matter.

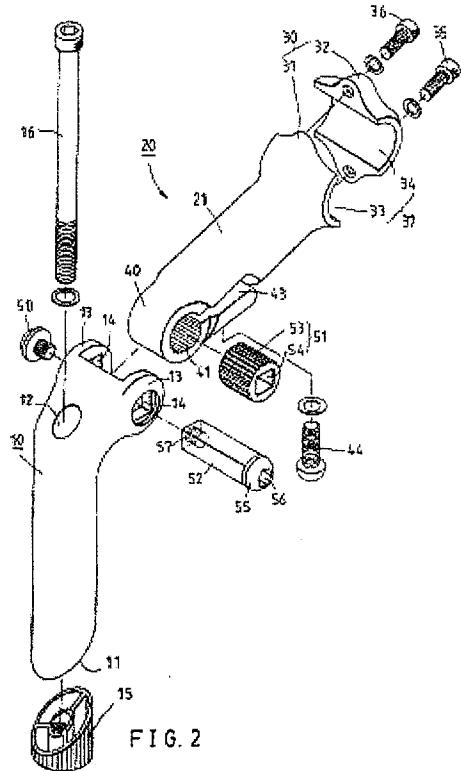
e. Dependent Claim 16

Claim 16 recites that the cylindrical member, a part of the mating element, is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member. As explained above, the pivot pin is the only component that can be considered to form the claimed mating element. Yue does not teach that the pivot pin is fixedly coupled a portion of either the blade (1) or the plate (2). Rather, the pivot pin is freely rotatably disposed through both the blade (1) and the plate (2). Accordingly, dependent claim 16 distinguishes over Yue and represents allowable subject matter.

B. Rejection Pursuant to 35 U.S.C. 103(a) Over Lai

1. The Scope And Content Of The Prior Art

Lai discloses an adjustable bicycle handlebar tube as shown in FIG. 2, which is reproduced herein, having a head tube (10) with two circular lugs (13) formed on one end, and an upright tube (20) with a pivoting portion (40) adapted to be disposed between the circular lugs (13) for mating the upright tube (20) to the circular lugs (13). The angle between the head tube (10) and the upright tube (20) is adjusted using a braking member (51) that is adapted to fit within a hole (41) formed in the pivoting portion (40) of the upright tube (20) before the upright tube (20) is disposed between the lugs (13), so that when the tube (20) is disposed between the lugs (13), a hole (54) of the braking member (51) is aligned with two holes (14) that extend through the lugs (13). A shaft (52) is then inserted into the hole (54) and the two holes (14) formed in the lugs (13). A bolt (58) is coupled to the shaft (52) to lock the head tube (10) in relation to the braking member (54). To lock the head tube (10) in relation to the upright tube (20), another bolt (44) is inserted through a portion of the upright tube (20) to cause serrated edges of the hole (41) and the braking member (51) to engage with one another.



and female connectors together. The Examiner states that “[a]lthough the material of the device is not specified, it would have been obvious to have formed the device from, e.g., titanium, since it has been held to be within the general skill of the a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.” (January 10, 2008 Office Action, pages 4-5). The Examiner further asserts that titanium is biocompatible, and that the screws (35, 36) of Lai are anchors that are capable of being secured to the spine.

3. The Claimed Invention Distinguishes Over Lai

a. Independent Claims 1, 42, 43, and 46

Independent claims 1, 42, 43, and 46 each recite a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members. The Examiner argues that the screws (35, 36) of Lai are anchors that can be secured to the spine. The screws (35, 36) are used by Lai to form a portion of the upright tube (20), and specifically are used to couple two fastening heads (31, 32) together. Due to the orientation of the screws, it would be impossible to use the screws to attach the device to a spine. Moreover, Lai does not teach or even suggest that screws (35, 36) are spinal anchors that are implantable in bone and configured to mate to at least one of the first and second elongate members, as required by independent claims 1, 42, 43, and 46. Lai is directed to a bicycle handlebar design, and does not ever mention spinal anchors or anything else implantable in bone. A spinal anchor is a term known to a person having ordinary skill in that art, and would not be understood to include any type of screw that can be used for any application, such a screw used to secure components of a bicycle handlebar.

Independent claims 1, 42, 43, and 46 also each recite that at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod. The term “spinal fixation rod” is well known to a person having ordinary skill in the art, and that certainly would not be understood to refer to just any type of rod, such as a tube of a bicycle handlebar. In addition, the bicycle handlebar of Lai is not biocompatible, and Lai certainly does not teach or even suggest forming the handlebars from any type of material that is compatible with living tissue. The Examiner assets that it would be obvious to form the handlebars of Lai from titanium as it is “a common material for devices of the type set forth by Lai for its light weight and strength and titanium is also biocompatible.” (January 10, 2008 Office Action, page 5). There are over 20 grades of titanium, not all of which are biocompatible. Thus it

would not be obvious to form the handlebars from the same type of titanium that would be used to form a medical implant.

Lai also cannot be relied on to formulate an obviousness rejection over the pending claims because the cited reference represents non-analogous art. In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is "analogous" if (1) the reference is within the field of the inventor's endeavor, and if it is not then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved.

Lai is not within the field of the inventor's endeavor. Lai is directed to a bicycle handlebar. The present invention, on the other hand, is directed toward implantable devices and methods for spinal fixation. No person having ordinary skill in the art would rely on a reference directed toward *a bicycle handlebar* to form a device for *spinal fixation*. These are distinct devices that are used for very different purposes.

Lai is also not reasonably pertinent to the problem to be solved, namely spinal fixation. Applicants refer the Examiner to MPEP 2141.01(a) and *In re Clay*, 966 F.2d 656, 659 ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.") The subject matter of Lai would not have logically been brought the attention of the inventor of the claimed subject matter as no inventor working in the area of spinal fixation would logically look to bicycle parts to solve the pertinent problem. Futher, MPEP 2141.01(a)(IV) includes examples of analogy in the mechanical arts. For example, in *In re Oetiker*, 977 F.2d 1443),

Applicant claimed an improvement in a hose clamp which differed from the prior art in the presence of a preassembly "hook" which maintained the preassembly condition of the clamp and disengaged automatically when the clamp was tightened. The Board relied upon a reference which disclosed a hook and eye fastener for use in garments, reasoning that all hooking problems are analogous. The court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary

skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments.

Like the above-referenced case, while the Examiner may argue that Lai is analogous because it addressed an adjustable connection, an inventor seeking to solve a problem regarding spinal fixation would not be reasonably be expected or motivated to look to a bicycle part in solving that problem. Accordingly, the bicycle handlebars of Lai are not within the field of inventors' endeavor, namely spinal fixation. Lai is therefore non-analogous art that cannot be relied on to formulate an obviousness rejection.

Accordingly, claims 1, 42, 43, and 46 distinguish over Lai and represent allowable subject matter. Claims 2, 13-20, 48, and 49 are allowable at least because they depend from allowable claims 1 and 46.

C. Rejection Pursuant to 35 U.S.C. 103(a) Over Yue

I. The Examiner's Rejection

Claims 8, 10, 47, and 50 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,007,536 of Yue. The Examiner asserts that Yue discloses the claimed invention except for the device being comprised of rods (or plates) instead of one rod and one plate. The Examiner argues that "given the disclosure of both a rod and a plate, it would have been obvious to a person of ordinary skill in the art, to have configured the device with two rods (or plates) instead of one rod and one plate, in order to address the exigencies of surgical necessity of patient anatomy." (January 10, 2008 Office Action, page 5).

2. The Claimed Invention Distinguishes Over Yue

a. Claims 8 and 10

At the outset, Applicants note that claims 8 and 10 depend from claim 1, and thus distinguish over Yue for all of the reasons discussed above with respect to claim 1. Claims 8 and 10 further distinguish over Yue because Yue cannot be modified as suggested by the Examiner because such a modification is specifically contrary to the teachings of Yue. No person having ordinary skill in the art would modify the side plate (2) or the blade (1) of Yue to both be a spinal rod or a spinal plate. Such a modification is specifically contrary to the purposes of Yue. As explained in Yue, the blade portion (1)

is "fashioned to gain fixation in cancellous or spongy bone by virtue of its flat shape and slightly curved edges." (see Col. 3, lines 12-15 of Yue). Thus, Yue specifically forms the blade portion (1) with a flattened shape for specific, advantageous reasons, and no person having ordinary skill in the art would modify the shape of the blade portion (1) of Yue to have anything other than a flattened shape. In addition, the side plate (2) is in the form of a flattened plate for specific reasons, namely to allow the plate (2) to lie flush with the bone after implantation, and no person having ordinary skill in the art would modify the plate (2) in the form of a rod. Thus, claims 8 and 10 further distinguish over Yue and represent allowable subject matter.

b. Claims 47 and 50

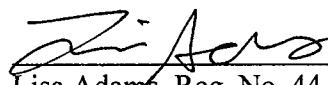
Claims 47 and 50 depend from claim 46, but independent claim 46 is not rejected over Yue because Yue does not teach a clamping mechanism formed on a terminal end of a first elongate element, as required by claim 46. Thus, the Examiner's rejection of claims 47 and 50 is flawed and should be withdrawn.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

Date: June 10, 2008


Lisa Adams, Reg. No. 44,238
Attorney for Applicant(s)

Nutter McClellan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
Tel: (617)439-2550
Fax: (617)310-9550

IX. APPENDIX A: CLAIMS ON APPEAL

1. (Previously Presented) A spinal fixation system, comprising:
 - a first elongate member having a female connector with opposed arms and a second elongate member having a male connector adapted to mate to the female connector, the first and second elongate members coupled to one another such that the first and second elongate members are angularly adjustable relative to one another;
 - a mating element adapted to extend through the male and female connectors;
 - a fastening element adapted to mate to the male connector to cause the male connector to engage the mating element and lock the elongate members in a fixed position relative to one another; and
 - a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.
2. (Previously Presented) The spinal fixation system of claim 1, wherein angular adjustment of each elongate member is limited to a single plane.
- 3-6. (Cancelled).
7. (Previously Presented) The spinal fixation system of claim 1, wherein the first and second elongate members each comprise a biocompatible, implantable spinal fixation rod.
8. (Previously Presented) The spinal fixation system of claim 1, wherein the first elongate member is a spinal fixation plate and the second elongate member is a biocompatible, implantable spinal fixation rod.
9. (Previously Presented) The spinal fixation system of claim 1, wherein the first elongate member is a biocompatible, implantable spinal fixation rod and second elongate member is a spinal fixation plate.
10. (Previously Presented) The spinal fixation system of claim 1, wherein the first elongate member has a diameter that is different than a diameter of the second elongate member.

11-12. (Cancelled).

13. (Previously Presented) The spinal fixation system of claim 1, wherein the opposed arms define a recess therebetween for receiving the male connector.

14. (Previously Presented) The spinal fixation system of claim 1, further comprising a bore extending through the opposed arms on the female connector and through the male connector, and the mating element extending through the bore for mating the male and female connectors to one another.

15. (Previously Presented) The spinal fixation system of claim 14, wherein the mating element comprises a cylindrical member, the cylindrical member being adapted to allow at least one of the first and second elongate members to rotate thereabout.

16. (Previously Presented) The spinal fixation system of claim 15, wherein the cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member.

17. (Previously Presented) The spinal fixation system of claim 16, wherein the fastening element is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector.

18. (Previously Presented) The spinal fixation system of claim 17, wherein the fastening element comprises a slot extending through the male connector such that the male connector is in the form of a clamp, and wherein the fastening element is adapted to engage the male connector to clamp the cylindrical member within the bore.

19. (Previously Presented) The spinal fixation system of claim 18, wherein the fastening element comprises a threaded member.

20. (Previously Presented) The spinal fixation system of claim 1, wherein the female connector and male connector of the first and second elongate members rotate about a central axis extending substantially perpendicular to an axis of each first and second elongate members.

21-41. (Cancelled).

42. (Previously Presented) A spinal fixation system, comprising:

first and second elongate members, each having a connecting feature formed on a terminal end thereof, the connecting features being coupled to one another such that the first and second elongate members are angularly adjustable relative to one another along a plane;

a mating element adapted to extend through the first and second elongate members;

a fastening element adapted to extend into at least one of the connecting features along an axis that is substantially parallel to the plane to cause at least one of the connecting features to engage with the mating element to lock the first and second elongate members in a fixed position relative to one another; and

a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.

43. (Previously Presented) A spinal fixation system, comprising:

first and second elongate members coupled to one another such that the first and second elongate members are angularly adjustable relative to one another, the angular adjustability of each elongate member being limited to a single plane;

a mating element adapted to extend through the first and second elongate members;

a fastening element adapted to cause at least one of the first and second elongate members to engage the mating element to lock the elongate members in a fixed position relative to one another, the fastening element extending along an axis that is substantially parallel to the single plane of angular adjustability of each elongate member; and

a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.

44-45. (Cancelled).

46. (Previously Presented) A spinal fixation system, comprising:

a first elongate element having a clamping mechanism formed on a terminal end thereof;

a second elongate element having a terminal end adapted to be received by the clamping mechanism on the first elongate element;

a fastening element adapted to engage and close the clamping mechanism such that the second elongate member can be maintained in a fixed position relative to the first elongate member; and

a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.

47. (Previously Presented) The spinal fixation system of claim 46, wherein the first elongate element has a diameter different from a diameter of the second elongate element.

48. (Previously Presented) The spinal fixation system of claim 46, wherein the first elongate element has a diameter that is the same as a diameter of the second elongate element.

49. (Previously Presented) The spinal fixation system of claim 46, wherein the terminal end of the second elongate element is positioned at an angle relative to a longitudinal axis of the second elongate element.

50. (Previously Presented) The spinal fixation system of claim 49, wherein the angle is about 90°.

51-59. (Cancelled).

X. APPENDIX B: EVIDENCE

No evidence submitted.

XI. APPENDIX C: RELATED PROCEEDINGS

No related proceedings.

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